

**REMARKS/ARGUMENTS**

Applicant has reviewed and considered the Office Action dated July 1, 2004 and cited reference therein.

Claims 5-8 are pending in the present application.

**Rejection of Claims 5-through 8 under 35 U.S.C. 103(a)**

Claims 5-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,653,493, issued to Serhan (hereinafter "Serhan"). Applicant respectfully traverses the rejection for the following reasons.

The present invention pertains to methods for treating a subject for restenosis in a tissue wherein smooth muscle cell migration occurs following angioplasty. The method is accomplished by administering a composition comprising an effective amount of a lipoxin A<sub>4</sub> compound and pharmaceutically acceptable salts, esters, amides, and prodrugs thereof to the subject, such that restenosis in a tissue wherein smooth muscle cell migration occurs following angioplasty is prevented, reduced, or inhibited. In one embodiment, the lipoxin A<sub>4</sub> compound is LXA<sub>4</sub> or 15-R/S- methyl, LXA<sub>4</sub>.

The present invention also pertains to methods for treating a subject for restenosis in a tissue wherein smooth muscle cell migration occurs following angioplasty. The method is accomplished by administering a composition comprising an effective amount of a 15-epi-lipoxin A<sub>4</sub> compound and pharmaceutically acceptable salts, esters, amides, and prodrugs thereof to the subject, such that restenosis in a tissue wherein smooth muscle cell migration occurs following angioplasty is prevented, reduced, or inhibited. In one embodiment, the 15-epi-lipoxin A<sub>4</sub> compound is 15-epi-16- (*para*-fluoro)-phenoxy-lipoxin A<sub>4</sub>.

Serhan does not teach or suggest, provide any motivation or an expectation of success methods to treat restenosis in a tissue wherein smooth muscle cell migration occurs *following angioplasty* with a lipoxin A<sub>4</sub> compound or a 15-epi-lipoxin A<sub>4</sub> compound.

It is well settled that it is not proper to selectively extract individual elements from a reference and then combine those selectively extracted elements to arrive at a claimed combination. Rather in considering the elements within the reference, the reference must be considered as a whole, it being impermissible to pick and choose from a reference only so much of it as will support a given position. *In re Wesslau*, 353, F.2d 238, 147 USPQ 391 (CCPA 1965); *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984).

There is a rigorous requirement that there must be some motivation, suggestion or teaching of the desirability for selecting the elements and combining those elements in the specific combination of the invention, and the motivation, suggestion or teaching must be disclosed in the prior art. *In re Kotzab*, 217 F.3d 1365, 54 USPQ2d 1308, 1316 (Fed. Cir. 2000); *In re Oetiker*, 977 F.2d 14343, 24 USPQ2d 1443 (Fed. Cir. 1992). In the absence of such motivation, suggestion or teaching, it is immaterial that some, or even all, of the elements in a specific combination of an invention are known in the prior art.

This is the case at hand. Serhan does not teach or suggest, provide any motivation or an expectation of success that any lipoxin compound could be used to treat restenosis in a tissue wherein smooth muscle cell migration occurs following angioplasty.

As clearly stated in *In re Rouffet*, 149 F.3d 1350, 1357, 47 USPQ2d 1453 (Fed. Cir. 1998):

As this court has stated, "virtually all [inventions] are combinations of old elements." *Environmental Designs, Ltd. v. Union Oil Co.*, 713F2d 693, 698,218 U.S.P.Q. (BNA) 865, 870 (Fed. Cir. 1983); see also *Richdel, Inc. v. Sunspool Corp.*, 714 F2d 1573, 1579-80, 219 U.S.P.Q. (BNA) 8, 12 (Fed. Cir. 1983) ("Most, if not all, inventions are combinations and mostly of old elements."). Therefore an examiner may often find every element of a claimed invention in the prior art. If identification of each claimed element in the prior art were sufficient to negate patentability, very few patents would ever issue. Furthermore, rejecting patents solely by finding prior art corollaries for the claimed elements would permit an examiner to use the claimed invention itself as a blueprint for piecing together elements in the

prior art to defeat the patentability of the claimed invention. Such an approach would be "an illogical and inappropriate process by which to determine patentability." *Sensonics, Inc.. v. Aerisonic Corp.*, 81 F.3d 1566, 1570, 38 U.S.P.Q.2D (BNA) 1551,1554 (Fed. Cir. 1996).

and:

To prevent the use of hindsight based on the invention to defeat patentability of the invention, this court requires the examiner to show a motivation to combine the citations within the reference to create the case of obviousness. In other words, the examiner must show reasons that the skilled artisan, confronted with the same problems as the inventor and with no knowledge of the claimed invention, would select the elements from the cited prior art reference for combination in the manner claimed.

Serhan provides no such motivation to use any lipoxin compound could be used to treat restenosis in a tissue wherein smooth muscle cell migration occurs following angioplasty.

Serhan does not provide a motivation, suggestion or teaching, and no showing has been made otherwise identifying in Serhan such a motivation, suggestion or teaching, for selecting elements from the cited reference to render obvious the methods recited in Claims 5 through 8, and the invention cannot be used as a blueprint for identifying a suggestion or motivation.

As stated in *In re Dembiczaik*, 175 F.3d 994, 999, 50 U.S.P.Q.2d (BNA) 1614 (Fed. Cir. 1999):

Our case law makes clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references. See, e.g., *C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1352, 48 U.S.P.Q.2D (BNA) 1225, 1232 (Fed. Cir. 1998) (describing "teaching or suggestion or motivation [to combine]" as an "essential evidentiary component of an obviousness holding"); *In re Rouffet*, 149 F.3d 1350, 1359, 47 U.S.P.Q.2D (BNA) 1453, 1459 (Fed. Cir. 1998) ("the Board must identify specifically... the reasons one of ordinary skill in the art would have been motivated

to select the references and combine them"); *In re Fritch*, 972 F2d 1260, 1265, 23 U.S.P.Q.2D (BNA) 1780, 1783 (Fed. Cir. 1992) (examiner can satisfy burden of obviousness in light of combination "only by showing some objective teaching [leading to the combination]"); *In re Fine*, 837F.2d 1071, 1075, 5 U.S.P.Q.2D (BNA) 1596, 1600 (Fed. Cir. 1988) (evidence of teaching or suggestion "essential" to avoid hindsight); *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 297, 227 U.S.P.Q. (BNA) 657, 667 (Fed. Cir 1985) (district court's conclusion of obviousness was error when it "did not elucidate any factual teachings, suggestions or incentives from this prior art that showed the propriety of combination"). See also *Graham*, 383 U.S. at 18, 148 U.S.P.Q. (BNA) at 467 ("strict observance" of factual predicates to obviousness conclusion required). Combining prior art references without evidence of such a suggestion, teaching, or motivation simply takes the inventor's disclosure as a blueprint for piecing together the prior art to defeat patentability--the essence of hindsight. See, e.g., *Interconnect Planning Corp. v. Feil*, 774 F2d 1132, 1138, 227 U.S.P.Q. (BNA) 543, 547 (Fed. Cir. 1985) ("The invention must be viewed not with the blueprint drawn by the inventor, but in the state of the art that existed at the time."). In this case the Board fell into the hindsight trap.

It is believed that all of the issues raised in the Office Action have been addressed herein. Should the Examiner maintain the rejection of any of the pending claims, it is respectfully requested that it be pointed out with particularity how the cited reference meets each and every term of each claim with respect to which rejection is maintained, and if the rejection is based on obviousness, identification of the specific motivation, suggestion or teaching in the reference for combining elements in the specific combination off the invention.

Reconsideration and withdrawal of the pending rejection are respectfully requested.

**Conclusion**

In view of the above, it is respectfully submitted that the present application is in condition for allowance. Reconsideration of the present application and a favorable response are respectfully requested. If a telephone conference would be helpful in resolving any remaining issues, please contact the undersigned at 612-340-8819.

Respectfully submitted,

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